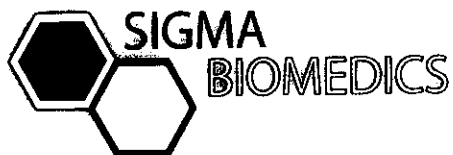


K060179

FEB 8 2006



510(k) Summary

Sigma Biomedics, Inc.
65 E. Palatine Rd., Bldg.#201
Prospect Heights, IL 60070
847-419-0669

Name of Contact person: Kim Antol

Date Summary was prepared: January 9, 2006

Name of Device

| | |
|-------------------------|---|
| Trade/Proprietary Name: | Bio-Ray SDX Digital X-Ray System |
| Common/Usual Name: | Intraoral X-Ray Sensor |
| Classification Name: | Extraoral Source Dental X-Ray, Digital System |

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]

Description of the Device:

Digital Dental Intraoral X-Ray Sensor

This device is intended to be used for the dental radiographic examination for the diagnosis of diseases of the teeth, jaw, and oral structures.

Your Digital Imaging Specialists

65 E. Palatine Rd., #201, Prospect Heights, IL 60070, (800) 331-6077, (847) 419-0669, Fax-(847) 419-0675



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2006

Ms. Kim Antol
President
Sigma Biomedics, Inc.
65 E. Palatine Rd., Bldg. 201
PROSPECT HEIGHTS IL 60070-1845

Re: K060179
Trade/Device Name: BIO-Ray SDX Digital
X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: MUH
Dated: January 20, 2006
Received: January 24, 2006

Dear Ms. Antol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060179

Device Name: BIO-Ray SDX Digital X-Ray system

Indications For Use:

The BIO-RAY SDX digital x-ray system is intended to be used with standard x-ray systems to collect dental x-ray photos and convert them into electronic data that may be stored, viewed, and manipulated by dentists for the diagnosis of the teeth, jaw and oral structures with the use of computer imaging software provided by other 3rd parties, readily available from numerous sources.

This device is only to be sold as a prescription device sold to doctors or dental dealers selling directly to doctors.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number _____

K060179